IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

MICHAEL BAZZREA, *et al.*,	:	
	:	
Plaintiffs,	:	
v.	:	
	:	**Case No.: 3:22-cv-265**
LLOYD AUSTIN, III, *et al.*,	:	
	:	
Defendants.	:	
	:	

PLAINTIFFS' REPLY BRIEF

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INTRODUCTION

Defendants' November 28, 2022 response in opposition ("Opp."), ECF 56, to Plaintiffs' November 7, 2022 motion for an evidentiary hearing ("Mot."), ECF 50, concedes many of Plaintiffs' central allegations, in particular, that: (1) nearly half of their total inventory of purportedly licensed vaccines are, in fact, not licensed; (2) Defendants have mandated unlicensed bivalent vaccines; and (3) the "digital tools" are authentic and were used to evaluate and deny the religious accommodation requests ("RARs") of Plaintiffs and Coast Guard Class Members. Defendants' response demonstrates that Plaintiffs' statutory claims cannot be dismissed as moot, which is the primary reason for which Plaintiffs requested a hearing to decide this fundamental jurisdictional issue. The response also provides the basis for the court to grant summary judgment finding that Defendants have mandated unlicensed bivalent vaccines from lots GH9697, GH9702, and GJ6665 (the "G Lots").

Based on these concessions and the official records and other documents submitted by Plaintiffs, this Court could make the findings requested by Plaintiffs without a hearing. To the extent the Court deems the record to be insufficient to make these findings, Plaintiffs urge the Court to hold a hearing on those issues.

I. DEFENDANTS HAVE CONCEDED THAT NEARLY HALF OF THE PURPORTED LICENSED DOSES ARE NOT LICENSED.

In the Hearing Motion, Plaintiffs presented conclusive evidence that over 49,000 out of Defendants' total inventory of 50,000+ FDA-licensed products—and of the "Comirnaty-labeled, BLA-approved" doses—were in fact unlicensed and

misbranded. The majority of these were also expired or even adulterated, and thus not only could not be mandated, but could not be sold or administered to anyone.

Defendants now accuse Plaintiffs of "attempt[ing] to concoct a convoluted factual dispute regarding the 'legal status' of specific lots of Comirnaty." Opp. at 3. Yet on the very next page, in a lengthy footnote, Defendants concede that Plaintiffs were completely correct with respect to the G Lots, Opp. at 4 n.2, which represented nearly half of their total inventory as of October 18, 2022. *See* ECF 50-3, Rans Decl., Ex. A (49,410 doses of Grey Cap COMIRNATY® and 770 doses of SPIKEVAX®, for a total of 51,180). With this concession, the total of purportedly "licensed" vaccines has been reduced to just over 28,000, if one is willing to accept the Defendant's claims at face value in spite of their history of mandating unlicensed products during this litigation and continuous "human errors" regarding the presence of licensed products. *See* ECF 56-1, Rans Decl., Ex. A.[1]

Plaintiffs' Hearing Motion, which Defendants claim offer "no credible basis" to hold the requested hearing, Opp. at 2, forced Defendants' to admit that they

[1] In a November 3, 2022, hearing before a federal court in a related case, Defendants' counsel acknowledged that EUA products cannot lawfully be mandated, but insisted that "we're only mandating the fully approved" product. *John DOE #1-#14 v. Austin*, 572 F.Supp.3d 1224 (N.D. Fla. 2021), Hearing Tr., 52:18-19. This claim was made despite the fact that the FDA-licensed Purple Cap COMIRNATY® was not only not available, but did not exist because it was *never made*. *See* Mot. at 11 & n.7. Additionally, the assertion that the Defendants had fully-licensed product available for military Plaintiffs throughout the mandate is directly contradicted by the same government expert – Col. Rans – who averred in this case that the licensed COMIRNATY® gray cap wasn't even available for ordering until May 2022. *See* ECF 22-2, Rans Decl., ¶ 19.

were wrong about nearly half of their purported supply, and conversely, that Plaintiffs were (at least) half right.

II. DEFENDANTS DO NOT CONTEST THE AUTHENTICITY OR USE OF "DIGITAL TOOLS" TO EVALUATE RELIGIOUS ACCOMMODATION REQUESTS.

In light of Defendants' Response, there is no longer any dispute as to the authenticity of the "digital tools" included in the Hearing Motion. *See* Mot. at 19-21 (*discussing* ECF 50-1, Religious Accommodation Appeal Generator & ECF 50-2, Denial Letter Template). Defendants do not claim that these digital tools were not used in the evaluation of Plaintiffs and Coast Guard Class Members' RARs. Instead, the dispute appears to be over the factual issue of ***how*** the tools were used, and whether they resulted in "automatic" denials, as Plaintiffs and Members of Congress contend. This is exactly the type of factual issue that limited discovery and an evidentiary hearing would resolve.

III. BIOLOGICS EXPIRE AT THE LATEST ON THE DATE STATED ON FDA-APPROVED PRODUCT LABELING.

Defendants' erroneously claim that an April 14, 2022 FDA supplemental approval letter ("April 14 Letter"), *see* ECF 50-5, "supersede[s] any expiration date that may have been previously stamped on a vial or carton at the time of manufacture," Opp. at 13, and that there is "no requirement to include an expiration date" on the product labeling. *Id.* at 13 n.10 (*citing* 21 C.F.R. § 201.57).

Defendants' assertion is directly contradicted by the express terms of the Public Health Safety Act ("PHSA") and the Food and Drug Administration's ("FDA") own regulations. The PHSA requires that the "***the*** expiration date of the

biological product" must be "plainly marked" on "each package" of the biological product. 42 U.S.C. §262(a)(1)(B)(iii) (emphasis added). FDA regulations implementing this statutory requirement echo that "***[t]he*** expiration date" "shall appear" on "each container". 21 C.F.R. § 610.60(a) (emphasis added). Not "an" expiration date, but **the** one and only actual expiration date. This is the expiration date that doctors, pharmacists, and recipients or potential recipients will see and must be able to rely on.

Defendants do not cite any authority that would permit the FDA to waive or override a labeling requirement mandated by statute and FDA regulations, or the actual expiration date stated in the product labeling. The general requirements in the regulation cited for prescription drugs, 21 C.F.R. § 201.57, gives no indication that the FDA may override the expiration date stated on the product labeling and replace it with another one, whether stated in a letter, the manufacturer website, sky writing, or any other place. While this regulation does not list the expiration date as a requirement for the label, it does not purport to provide an exhaustive list of all requirements, nor does it supersede the more specific requirements for labeling biologics in 21 C.F.R. § 610.60. In any case, an FDA regulation cannot override the express statutory requirement in 42 U.S.C. § 262(a) that each package must state the expiration date.

Even if there were some legal basis for Defendants' claim that the FDA can waive clear, mandatory statutory requirements and replace "the expiration date" stated on the product label with another one that it approves by non-public letters

or by posting on a website, the FDA's litigation position is inconsistent with the actions of both the FDA and the manufacturer.

First, all of the FW Lots were in Pfizer's possession when the April 14 Letter was issued and remained there for several weeks until they were shipped to Defendants DOD and Coast Guard. In that time, Pfizer could have easily updated the expiration dates on the product labeling. The manufacturer did not do that, however.

Second, it would have been even easier for Pfizer to update the package insert to state the new expiration date or to state that the expiration date was three months later than that stated on the product label. An updated, currently effective package insert could have been posted to a website; yet (again) Pfizer chose not to do so.

Finally, all of the package inserts submitted by Pfizer for FDA review and FDA approval that were in effect both before and after April 14, 2022 continued to state that: "***Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vial and cartons***."[2] If the FDA had intended the April 14 Letter to override the "expiration date printed on the vial and cartons," the FDA could have directed Pfizer to make this change to the product label or package insert; yet (again) it (also) chose not do so.

[2] *See* ECF 50-10, Dec. 22, 2021 Comirnaty Tris/Sucrose Package Insert, at 13 (emphasis added); ECF 50-11, May 19, 2022 Comirnaty Tris/Sucrose Package Insert, at 27. The package inserts approved in July and August 2022 both contain the same language.

As discussed below, Plaintiffs rely solely on statutory requirements and official FDA records whose authenticity is not in dispute, namely, the expiration date stated on the FDA-approved product label, the FDA-approved package insert, and the FDA's own lot release letters. *See* ECF 50-5 (FW 1330 Lot Release Letter); ECF 50-6 (FW 1331 Lot Release Letter); ECF 50-7 (FW 1333 Lot Release Letter).

Neither Pfizer nor the FDA implemented the expiration date extension authorized in the April 14 Letter with respect to the FW Lots. Defendants have not offered any explanation for the conflict between the April 14 Letter, which does not specify the lots to which it applies, and the three sets of FDA official records before the Court that are specific to these lots. Accordingly, the FDA's position should be dismissed as an "irrelevant" "*[p]ost hoc* rationalization offered by the Government's counsel." *Univ. of Tex. M.D. Anderson Cancer Ctr. v. HHS*, 985 F.3d 472, 475 (5th Cir. 2021).

IV. MOST OR ALL FW LOTS AND SPIKEVAX® DOSES EXPIRED BEFORE THE DATE STATED ON PRODUCT LABEL.

In the Hearing Motion, Plaintiffs presented an official DOD record stating that DOD policy was that all COVID-19 vaccines were to be "ship[ped] refrigerated" from Fort Detrick, Maryland, to other U.S. facilities at "2C to 8C with a 10 week shelf life." ECF 50-4, Kupper Decl., ¶ 8 & Ex. C, Slide 18. None of the doses listed in the exhibit to the declaration of Colonel Tanya Rans appear to be stored at Fort Detrick. Based on this generally applicable policy, all of the doses at U.S. facilities would have been shipped refrigerated to these other locations from Fort Detrick, and they would have expired 10 weeks after shipment commenced.

Defendants do not even attempt to refute this policy. At most, they concede that the sworn testimony regarding the expired doses in Yuma, Arizona may be correct, but is irrelevant because Plaintiffs were not required to take these specific doses. Opp. at 14 n.11. Further, Defendants do not attempt to demonstrate that any of the expired doses listed in the Rans Declaration satisfied the pre-condition for the expiration date extension, namely, that they were continuously stored "between -90 ºC and -60 ºC." ECF 50-5, April 14 Letter, at 1.

The same conclusion likely applies to all of the Moderna SPIKEVAX® lots, which may be stored only 30 days (rather than 10 weeks) at refrigerated temperatures. *See* Ex. 1, Jan. 31, 2022 Moderna SPIKEVAX® Fact Sheet, at 3. All Moderna SPIKEVAX® doses listed in the Rans Declaration are stored at locations other than Fort Detrick, Maryland. If they were shipped refrigerated like the Pfizer/BioNTech products, then they expired 30 days after shipment to their current location. Plaintiffs respectfully submit that, at the evidentiary hearing, the burden will be on Defendants to demonstrate that this SPIKEVAX® is not expired.

V. OFFICIAL RECORDS SUBMITTED BY DEFENDANTS ARE CONTRADICTED BY MULTIPLE OFFICIAL RECORDS SUBMITTED BY PLAINTIFFS.

Defendants urge the Court to give the official records that they have submitted a "controlling presumption of regularity and good faith absent clear evidence to the contrary." Opp., at 9.[3] That is exactly what Plaintiffs have provided:

[3] Defendants also cite several cases that extend this presumption to declarations or affidavits of agency officials, *see* Opp. at 9-10, but these cases are inapposite. Ms. Burks' two declarations merely provided background information and

several official and publicly available agency records[4] that are due the same presumption of regularity and good faith as Defendants' submissions and that each provide clear and "direct evidence contradicting the Government's position." *U.S. v. O'Callaghan*, 500 F. App'x 843, 844 (11th Cir. 2012) (citation omitted). The presumption of regularity is not "irrebuttable," and the official records and credible testimony submitted by Plaintiffs contradicting the Defendants' position provide basis for the Court to order an evidentiary hearing to "look behind the presumption to the actual facts." *Bismullah v. Gates*, 501 F.3d 178, 186 (D.C. Cir. 2007).

Defendants also suggest that the official records relied on by Plaintiffs are inaccurate by pointing to a disclaimer on the NIH DailyMed website, which states that: "The 'in use' labeling on DailyMed may not be identical to the most recent FDA-approved labeling." DF Opp., at 12 n.7. This disclaimer does not affect Plaintiffs' arguments, which expressly acknowledged that they relied on previous, archived versions of the Pfizer Gray Cap Comirnaty package inserts that were in effect from December 22, 2021 through July 14, 2022[5] (*i.e.*, the time period from

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included lot release letters for "Comirnaty-labeled" lots FW1330 and FW1331. Plaintiffs do not dispute the contents of these lot release letters and in fact rely on their accuracy and authenticity.

[4] Plaintiffs' Hearing Motion relied on: (1) the FDA-approved product labels and package inserts; (2) the FDA lot release letters; (3) the FDA's STN numbers; (4) the CDC NDCs; (5) the identification of the FW and G Lots as EUA on the CDC website; and (6) the sworn testimony and official records submitted by Colonel Rans and Suzanne Burk. Defendants have not disputed the authenticity or accuracy of any of these official records.

[5] *See* ECF 50, PL Mot., at 12-13 (*discussing* ECF 50-10, Dec. 22, 2021 Comirnaty

when the FW Lots were manufactured through the date of delivery to the DOD). Defendants do not dispute the accuracy of these official records, nor identify any conflict between the archived versions on the NIH website or the FDA-approved documents.

VI. THE CDC WEBSITE ACCURATELY LISTED THE FW LOTS AS EUA LOTS.

Defendants state that "the CDC has updated the language on the website to clarify that it" lists both EUA and licensed lot numbers for the Pfizer and Moderna COVID-19 vaccines. *See* Opp. at 12 n.8. This does not refute the August 4, 2022 testimony of Lieutenant Mark Bashaw included in Plaintiffs' September 6, 2022 Reply Brief, *see* ECF 27-1, Coppin Decl., at 26 (Bashaw Decl., ¶¶ 10-11) that the CDC website previously stated that it listed only EUA lots and that Lot FW1331 was listed as one of the EUA Lots. In a subsequent declaration filed with the Hearing Motion, LT Bashaw reaffirmed his August 4, 2022 testimony. *See* ECF 50-17, Bashaw Decl., ¶ 8. Tellingly, Defendants do not dispute the accuracy of the CDC's previous description of the FW Lots as EUA lots.

VII. PLAINTIFFS' STATUTORY CLAIMS ARE NOT MOOT.

Defendants' response and the two declarations from Colonel Rans, *see* ECF 50-3, Rans Decl., Ex. A & ECF 56-1, Rans Decl., Ex. A, conclusively demonstrate that Defendants have in fact mandated unlicensed vaccines from three unlicensed

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Tris/Sucrose Package Insert & ECF 50-11, May 19, 2022 Comirnaty Tris/Sucrose Package Insert).

bivalent G Lots. Plaintiffs' statutory claims cannot be dismissed as moot, as Defendants urge, *see* Opp. at 3-5, because the mandate of a distinct, new product—the unlicensed, bivalent vaccine in the G Lots—is yet another repetition of the initial violations of 10 U.S.C. § 1107a in the September 14, 2021 Pfizer/BioNTech Interchangeability Directive, *see* ECF 1-7, and the May 3, 2022 Moderna Interchangeability Directive. *See* ECF 1-8.

All three of these distinct mandates of unlicensed EUA products applied to Plaintiffs and other Coast Guard Class Members. Thus, even if their statutory claims were otherwise moot (and they are not), Plaintiffs would qualify for "capable of repetition, yet evading review" exception to mootness because "there [is] a reasonable expectation that [Plaintiffs will] be subjected to the same action again." *Fla. Bd. of Bus. Regul. v. N.L.R.B.,* 605 F.2d 916, 920 (5th Cir. 1979) (citation and quotation marks omitted). It isn't just a "reasonable expectation;" Defendants did it, in full view of the Court.

Defendants' concession that the G Lots "were misidentified as Comirnaty," Opp. at 4-5 n.2, also does not constitute voluntary cessation that would moot Plaintiffs' statutory claims. (Indeed, it appears "unknown" if Defendants have given other members of the military not represented in this litigation any doses from these or other "misidentified" lots.) Defendants have also not repealed or rescinded their initial and earlier directives that unlicensed EUA products may be mandated. Indeed, Defendants continue to vigorously defend the legality of mandating EUA products. Thus, Defendants have not even attempted to carry their

"heavy burden of persuading the Court that the challenged conduct cannot reasonably be expected to start again." *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) (cleaned up).

Defendants also claim that Plaintiffs claims are moot because they can take "other BLA-approved, Comirnaty- or Spikevax-labeled lots, including those in the DOD's vaccines store whose 'legal status' Plaintiffs do not dispute." Opp. at 7. But Plaintiffs *do* challenge the legal status of all doses from the FW Lots. *See supra* Section III. Plaintiffs also allege—and provided convincing evidence—that all of the other purportedly FDA-licensed products are expired and/or adulterated, including the SPIKEVAX® doses that they claim to have. *See supra* Section IV.

Finally, Defendants claim that "Plaintiffs can obtain" FDA-licensed vaccines "in the community". Opp. at 4-5 n.2. Defendants have not, however, identified any such commercial sellers and Plaintiffs maintain, as they have since the inception of this litigation, that Defendants cannot simultaneously have these licensed products "available" when the Defendant FDA has statutorily determined that the products are "unavailable" for purposes of extending the EUAs for each manufacturers' (unlicensed) mirror products under 21 U.S.C. §360bbb-3. *See, e.g.*, Compl. ¶¶ 71-72, ECF 1; *see also* Plaintiffs PI Motion, ECF 17, § II.D, p. 35. As before, Plaintiffs have inquired without success whether any commercial pharmacy has these products in stock. Accordingly, there are no "other BLA-approved, Comirnaty- or Spikevax-labeled lots" available to Plaintiffs beyond those (yet again) conveniently identified by the Defendants for purposes of arguing

Plaintiffs' claims are moot.

VIII. DEFENDANTS' RESPONSE PROVIDES GROUNDS TO GRANT SUMMARY JUDGMENT ON PLAINTIFFS' STATUTORY CLAIMS.

Defendants' response also provides the basis for the Court to grant summary judgment finding that Defendants' have mandated unlicensed bivalent vaccines from the G Lots. The October 18, 2022 Rans declaration, *see* ECF 50-3, Rans Decl. & Ex. A, constitutes a binding admission that unlicensed bivalent EUA vaccines were included in the inventory of products that could be mandated until at least the date of the November 28, 2022 response. Defendants' explanation in a footnote that the G Lots were "misidentified as Comirnaty" due to "human error", Opp. at 4-5 n.2, at most addresses Plaintiffs' misbranding claims.

10 U.S.C. § 1107a does not include any exceptions for mistakes, nor does it include any intent element. It strictly prohibits the mandate of EUA products. There is only one exception—Presidential authorization—that does not apply here because Defendant Austin has never sought the appropriate Presidential waiver of Plaintiffs' informed consent rights. Now there is no longer any factual dispute that Defendants mandated the unlicensed EUA bivalent products in the G Lots because Defendants have been forced to publicly admit it due to Plaintiffs' diligence in holding the government to its own legal standards and regulations.

IX. CONCLUSION

This Court should grant Plaintiffs' Hearing Motion. In the alternative, Plaintiffs are entitled to a judicial finding that the Defendants have admitted to mandating unlicensed, bivalent gene therapy products and thereby violated

Plaintiffs' informed consent rights.

Dated: December 5, 2022

Respectfully Submitted,

/s/ Dale Saran
Dale Saran, Esq.
MA Bar #654781
19744 W 116th Terrace
Olathe, KS 66061
Telephone: 480-466-0369
Email: dalesaran@gmail.com

/s/ Brandon Johnson
Brandon Johnson
DC Bar No. 491370
/s/ Travis Miller
Travis Miller
Texas Bar #24072952
Defending the Republic
2911 Turtle Creek Blvd., Suite 300
Tel. (214) 707-1775
Email: bcj@defendingtherepublic.org
Email: twmlegal@gmail.com

/s/ Simon Peter Serrano
S. Peter Serrano, Esq.
WA Bar #54769
5238 Outlet Dr.
Pasco, WA 99301
Telephone: 530-906-9666
Email: pete@silentmajorityfoundation.org

/s/ J. Andrew Meyer
J. Andrew Meyer, Esq.
Fla Bar No. 0056766
FINN LAW GROUP, P.A.
8380 Bay Pines Blvd
St. Petersburg, Florida 33709
Tel.: 727-709-7668
Email: ameyer@finnlawgroup.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

This is to certify that on this 5th day of December, 2022, the foregoing Plaintiffs' Reply Brief was e-filed using the CM/ECF system.

Respectfully Submitted,

/s/ Brandon Johnson
Brandon Johnson